

51. *The catheter of claim 50 wherein the proximal segment further comprises a braid interposed between the inner proximal liner and the outer proximal cover.*

52. *The catheter of claim 50 wherein the proximal segment further comprises a coil interposed between the inner proximal liner and the outer proximal cover.*

53. *The catheter of claim 31 wherein the knit tubular member extends into the proximal segment.*

## REMARKS

Claims 1-22, 24-48, and 50-53 were pending in the present application. By virtue of this response, claims 16 and 43 have been cancelled, and claims 1, 17-22, 24, 31, and 44-48 have been amended. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

### **Concerning the drawings**

Applicants acknowledge receipt of form PTO-948. Applicants will submit corrected drawings to conform with the PTO-948 upon receipt of the Notice of Allowance.

### **Rejections under 35 U.S.C. §103**

A. The Office has rejected claims 1, 2, 6, 13, 16, 18, 19, 20, 21, 24, 27, 31, 34, 40, 43, 45-48, 50, 51, and 53 as allegedly being unpatentable over Cornelius *et al.* (U.S. Patent No. 5,338,295) in view of Andersen *et al.* (U.S. Patent No. 5,674,276). Claims 16 and 43 have been cancelled in this action.

In rejecting the claims, the Examiner stated on page 3, lines 7-12:

Cornelius does not disclose a knit tubular member being formed from a plurality of interlocking loops. Andersen et al. does teach a knit tubular member being formed

from a plurality of interlocking loops (fig 1a). It would have been obvious to one of ordinary skill in the art to modify the invention of Cornelius to include the knit formed from a plurality of interlocking loops as taught by Andersen et al. so that the knit has more structural integrity, therefore having a stronger wall but allowing flexibility.

Claim 1 has been amended to recite "an inner tubular liner in coaxial relationship with the knit tubular member, and an integral outer tubular cover extending over the knit tubular member" (for support, see page 6, lines 10-17). Cornelius, however, discloses a knit tubular member in which "[p]olyimide material 54 encases tubular braid 52 on both the inner and outer surfaces of braid 52" (emphasis added, column 3, lines 66-67 and Figure 3). Here, the knit tubular member is completely encapsulated within the polyimide material; this differs from the use of an inner tubular liner and an outer tubular cover extending over the knit tubular member. Using an inner tubular liner and a separate outer tubular liner allows significantly greater control over the catheter flexibility in having the ability to select outer tubular liners of different materials. (For support page 6, lines 18-23, lines 29 to page 7, line 2.) And this ability to select different materials for inner and outer liners allows a user to control the flexibility (see page 7, 7-10) to a degree which is simply not available by the mere encapsulation of the knit member with a uniform polyimide material. Cornelius is silent on the use of differing polyimide lining materials but from Figure 3, it appears that a single uniform material is used to encapsulate the knit members.

The Examiner stated that "[i]t would have been obvious to one of ordinary skill in the art to modify the invention of Cornelius to include the knit formed from a plurality of interlocking loops as taught by Andersen et al. so that the knit has more structural integrity." The Office Action states the combination in a conclusory fashion. There is no reason presented why one would combine the teachings in this way. Specifically, why would one of ordinary skill take a structure in a stent and place it in a catheter. It is a necessity in this type of rejection that the cited references have some teaching on this. Here, we have no such guidance. Without such guidance, the rejection is simply improper.

Moreover, Andersen teaches away from the modification of Cornelius. The knit member disclosed in Andersen is a knit which is formed from "rather loosely interlocked loops with selected, loop length. . . . This design facilitates wrapping the prosthesis into small size for delivery intralumenally" (column 4, lines 57-59). Why would one of ordinary skill choose a structure which is easily wrappable? And so, the knit member was never meant to become an integral part of the catheter, which is used merely as a delivery device, and the design of the knit was never meant to impart any structural strength to the catheter. (See column 9, lines 5-10 and lines 57-60.) In fact, the knit member does not impart any structural strength and flexibility to the outer sleeve member. Instead the "axially slid able sleeve member 34 . . . is placed over the graft 80 to constrain the self-expanding anchoring ends 82, 82' and a balloon wall portion formed of a co-knit tubular structure" (column 9, lines 21-24). As such, motivation is lacking to move this knitted member from the outside of the catheter to inbetween layers for the purpose of securing it.

In fact, one of the main purposes of the Andersen knit is to "produce clotting in a sufficiently short time [so] that excessive bleeding through the graft will not occur when the graft is placed inside the lumen. . . . Over time in the body, the graft accepts cells, endothelializes and becomes a patent portion of the artery." (See column 5, lines 1-6; also see column 9, line 60 to column 10, line 2.) As seen, the purpose of the expandable knit member is to be placed within a body lumen and become a permanent part of the body by producing clots on its surface and endothelializing.

Taking the knit member of Andersen and encapsulating it within the polyimide material of Cornelius would destroy the functionality of Andersen's knit member as described in Andersen. As such, there is no expectation of success in making the substitution as suggested by the Examiner. Moreover, the expandable nature of Andersen's knit member was to ease delivery to a site within a body lumen (column 4, lines 60-61) and was not designed to impart any structural strength or limitation to the catheter, which was merely a delivery device, but to expand and contract with the walls of the body lumen (see column 5, lines 21-27).

Therefore, Andersen fails to cure the defects of Cornelius, either alone or in combination, fails to teach or suggest the use of an integral outer tubular member as recited in claim 1 and fails to teach or suggest but teaches away from the substitution of the knit tubular member of Andersen into the catheter of Cornelius.

Independent claims 24 and 31, as amended, are also believed to be patentable over Cornelius and Andersen, either alone or in combination, for at least the same reasons that claim 1 is patentable.

Additionally, claims 2, 6, 13, 18, 19, 20, and 21 depend ultimately from claim 1; claim 27 depends from claim 24; and claims 34, 40, 45-48, 50, 51, and 53 depend ultimately from claim 31 and are all patentable over Cornelius and Andersen, either alone or in combination, for at least the same reasons that claims 1, 24, and 31 are patentable.

For the above reasons, Applicants respectfully request reconsideration and withdrawal of this final rejection under 35 U.S.C. §103.

**B.** The Office has rejected claims 3-5, 7-9, 14-15, 17, 22, 25-26, 32, 33, 35-37, 41, 42, 44, and 52 as allegedly being unpatentable over Cornelius *et al.* (U.S. Patent No. 5,338,295) in view of Andersen *et al.* (U.S. Patent No. 5,674,276), and further in view of Samson (U.S. Patent No. 5,702,373).

The disclosure of Samson (U.S. Patent No. 5,702,373), either alone or in combination, fails to cure the defects of Cornelius and Andersen, as discussed above. Claims 3-5, 7-9, 14-15, 17 and 22 depend ultimately from claim 1; claims 25-26 depend from claim 24; and claims 32, 33, 35-37, 41, 42, 44, and 52 depend ultimately from claim 31 and all these claims are believed patentable for at least the same reasons that claims 1, 24, and 31 are patentable over Cornelius and Andersen.

For the above reasons, Applicants respectfully request reconsideration and withdrawal of this final rejection under 35 U.S.C. §103.

C. The Office has rejected claims 10-12, 28-30, 38-39 as allegedly being unpatentable over Cornelius *et al.* (U.S. Patent No. 5,338,295) in view of Andersen *et al.* (U.S. Patent No. 5,674,276), and further in view of Samson (U.S. Patent No. 5,702,373) as applied to claims 3-5, 7-9, 14-15, 17, 22, 25-26, 32, 33, 35-37, 41, 42, 44, and 52 as above, and further in view of Samson *et al.* (U.S. Patent No. 5,549,109).

The disclosure of Samson (U.S. Patent No. 5,549,109), either alone or in combination, fails to cure the defects of Cornelius, Andersen, and Samson (U.S. Patent No. 5,702,373), as discussed above. Claims 3-5, 7-9, 14-15, 17 and 22 depend ultimately from claim 1; claims 25-26 depend from claim 24; and claims 32, 33, 35-37, 41, 42, 44, and 52 depend ultimately from claim 31 and all these claims are believed patentable for at least the same reasons that claims 1, 24, and 31 are patentable over Cornelius, Andersen, and Samson (U.S. Patent No. 5,702,373).

For the above reasons, Applicants respectfully request reconsideration and withdrawal of this final rejection under 35 U.S.C. §103.

### **CONCLUSION**

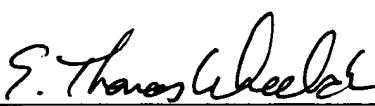
Applicant has, by way of the amendments and remarks presented herein, made a sincere effort to overcome rejections and address all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 290252021800. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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By:

  
Johny U. Han  
Registration No. 45,565

28,525

  
Morrison & Foerster LLP  
755 Page Mill Road  
Palo Alto, California 94304-1018  
Telephone: (650) 813-5786  
Facsimile: (650) 494-0792